



**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Georg **BERGER**, Heidi **MARX**, Christian **JAEGER** and Jutta **PAULI**

Application No.: 10/689,221

Filed: October 20, 2003

For: **POWDER MIXTURE FOR RESORBABLE CALCIUMPHOSPHATE BIOCEMENTS**

Attorney Docket No.: 3975.025

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.97 and §1.98**

**Mail Stop** \_\_\_\_\_  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 56, Applicants hereby notify the U.S. Patent and Trademark Office of the following documents for the above-identified application which were cited in the specification of the present invention and/or by the Examiner in the corresponding German application. Copies of the documents set forth below and listed on the attached Form PTO-1449, are provided herewith.

1. European Patent No. 0 237 043 B1
2. European Patent No. 0 541 546 B1
3. European Patent No. 1 153 621 A1
4. World Patent No. 99/49906
5. German Patent No. DE 40 16 135 A1
6. U.S. Patent 6,117,456
7. U.S. Patent 6,495,156 B2

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8. U.S. Patent 5,092,888
9. World Patent No. 91/07357

The relevancy of the non-English references is discussed below.

**Document 1**

The relevancy of Document 1 is discussed at paragraph 2 of the present specification. Applicants are not aware of any English language document corresponding to Document 1, but an English language abstract is attached.

Document 1 concerns a sheet material which contains calcium phosphate and which is compatible with a biological medium. It consists of a main body which contains, as main constituent, calcium orthophosphate and on which there is situated at least one outer sheet releasing calcium ions, the release of calcium from the sheet being greater than the release of calcium from the main body. The sheet material, which can be used as a temporary or permanent bone replacement substance, is produced by treatment with an acid or application of a sheet containing calcium compounds and subsequent heating between 400 and 1000°C.

**Document 2**

The relevancy of Document 2 is discussed at paragraph 3 of the present specification. Applicants are not aware of any English language document in the patent family of Document 2, other than Document 9 which is in the family and contains an English language abstract.

**Document 3**

Document 3 was cited as mere technical background in the German PTO. Document 7 is attached as an English language document in the patent family of Document 3.

Document 3 discloses a powder mixture with a high compression strength comprises tricalcium phosphate (TCP), 30-70% of which being of particle size 0.1-7 microns and 10-60% being 40-100 microns in size, precipitated hydroxyapatite (PHA), comprising a cation-defined HA, and a further phosphorus-containing inorganic compound(s). Powder mixture comprises tricalcium phosphate (TCP), 30-70% of which being of particle size 0.1-7 microns and 10-60% being 40-100 microns in size, precipitated hydroxyapatite (PHA), comprising a cation-defined HA of formula (I), and a further phosphorus-containing inorganic compound(s) (II).

$$\text{Ca}_{8.75}\text{V}(\text{Ca})_{1.25}((\text{HPO}_4)_{5.5-x}(\text{CO}_3)_{0.5})(\text{OH})_x\text{V}(\text{OH})_{2-x} \quad (\text{I}) \quad x = 0-2.$$

**Document 4**

Document 4 was cited as mere technical background in the German PTO. An English language Abstract can be found on the face of Document 4. The invention relates to biologically degradable calcium phosphate cement, especially mixtures of powders which contain calcium phosphate and which are of a different stoichiometric composition, exhibiting improved properties. The inventive mixtures all contain tricalcium phosphate (TCP) and one or more other compounds which contain phosphate and which are of a different composition, whereby the

TCP portion is available in a well-defined range of particle sizes.

#### Document 5

Document 5 was cited as mere technical background in the German PTO. Disclosed is a hardening material comprising (a) a powder component composed of a powdery mixture of tetracalcium phosphate and calcium phosphate having a Ca/P atomic ratio lower than 1.67 and (b) a liquid component composed of a colloidal aqueous solution comprising solid colloid particles dispersed in an aqueous medium, wherein said components (a) and (b) are independently packed and both the components are mixed for hardening. This hardening material can give a hardened body having a high strength without showing any harmful action on a living body. Accordingly, this hardening material is especially effectively used for the restoration of a hard tissue of a living body.

#### Document 9

Document 9 is a member of the family of Document 2, in which claims can be found which have been translated into the English language.

A vitreous or vitreous-crystalline, rapidly dissolving material has the following composition (wt.%) before combustion: 20 - 55 CaO, 5 - 25 Na<sub>2</sub>O, 0.01 - 15 K<sub>2</sub>O, 0 - 15 MgO, 30 - 50 P<sub>2</sub>O<sub>5</sub>, 0 - 15 SiO<sub>2</sub>, 0 - 40 Na<sub>2</sub>SO<sub>4</sub> and/or K<sub>2</sub>SO<sub>4</sub>. The new material can be obtained in vitreous or vitreous-crystalline form, depending on the cooling conditions. As a spontaneously

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crystallized glass ceramic, it contains the rhenanite phase, 'A' phase, 'X' phase and/or their mixed crystals. The material is both bioactive and biocompatible and dissolves rapidly. It can be used directly and with other materials as an implant for temporary bone replacement and to induce growth of connective tissue, and as a fertilizer and fodder material.

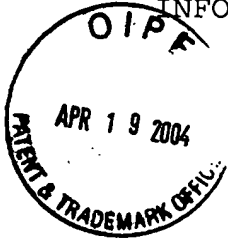
The present Information Disclosure Statement is being filed after three months from the application's filing date but before the mailing date of the first Office Action on the merits, therefore no Certification Under 37 C.F.R. §1.97(e) or fee under 37 C.F.R. §1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedated or otherwise remove any listed document as a competent reference against the claims of the present application.

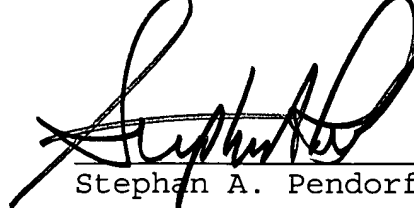
Applicant respectfully requests that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

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Respectfully submitted,

  
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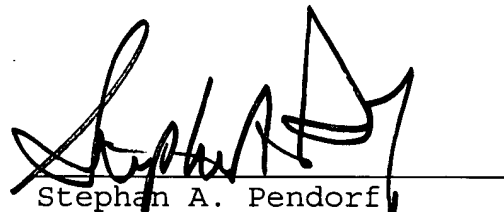
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Dated: April 15, 2004

**CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE**

I hereby certify that the foregoing INFORMATION DISCLOSURE STATEMENT Form PTO-1449, including nine (9) documents, for U.S. Application No. 10/689,221 filed October 20, 2003, were deposited in first class U.S. mail, postage prepaid, P.O. Box 1450, Alexandria, VA 22313-1450, on **April 15, 2004**.

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application, except for the issue fee, without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

  
Stephan A. Pendorf

# INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Docket Number (Optional)

3975.026

Application Number

10/689,221

Applicant(s)

Georg Berger et al.

Filing Date

10/20/2003

Group Art Unit

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		6,495,156 B2	12/17/2002	Wenz et al.	A61F	2/28	
		5,092,888	3/3/1992	Iwamoto et al.	A61F	2/28	
		6,117,456	9/12/2000	Lee et al.	A61K	47/02	



## FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
		0 237 043 B1	6/3/1992	Europe	A61L	27/00		✓
		0 541 546 B1	10/5/1994	Europe	C03C	3/16		✓
		1 153 621 A1	11/14/2001	Europe	A61L	27/12		✓
		99/49906	10/7/1999	World	A61L	25/00		✓
		40 16 135 A1	11/22/1990	Germany	A61L	25/00		✓

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)


EXAMINER

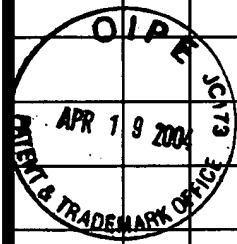
DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>	Docket Number (Optional) 3975.025	Application Number 10/689,221
	Applicant(s) Georg Berger et al.	
	Filing Date 10/20/2003	Group Art Unit

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**FOREIGN PATENT DOCUMENTS**

REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
	91/07357	5/30/1991	World	C03C	3/16		✓

**OTHER DOCUMENTS** *(Including Author, Title, Date, Pertinent Pages, Etc.)*


EXAMINER	DATE CONSIDERED
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